Integrating Toxicological Assessments in Material Selection for Apple Products

Rob Guzzo, Mike Werner, Art Fong, Lida Tan, Thomas Ebert

September 2016

Overview

A great deal of care and research go into choosing materials for Apple products to ensure manufacturing workers, customers, and recyclers can use and handle Apple products safely. Consideration of the toxicological profile of materials is a key component of Apple's material selection process during new product development. All materials must meet Apple specifications on substances that can be potentially hazardous, and undergo extensive materials characterization testing to demonstrate conformity to Apple specifications. In addition, Apple uses Full Material Disclosure (FMD), a process where material suppliers are asked to provide the entire chemical composition of all homogenous materials, along with materials characterization testing, to enable Apple toxicologists to conduct comprehensive hazard and risk assessments. Leveraging rapid toxicological assessments ensures that materials with unacceptable toxicological profiles are not permitted for use in Apple products.

Apple's Environmental Priorities

In 2013, Apple set three priorities for environmental responsibility to focus on areas where it could make the most impact. These include:

- Reducing Apple's impact on climate change by using renewable energy sources and driving energy efficiency in its products and facilities.
- Conserving precious resources by using more recycled and renewable content in its products, and increasing the supply of renewable resources.
- Identifying, developing, and utilizing safer materials in its products and processes.

Apple believes that reducing the use of hazardous substances in materials is essential to ensure the safety of workers who manufacture its products, customers who use its products, and recyclers who handle its products at the end of the products' useful life. This commitment to the safety of workers, customers and recyclers has driven Apple to lead the electronics industry in phasing out hazardous substances from its products.

History of Restricting Hazardous Substances

Apple initiated its program on safer materials in the early 1990s, when some heavy metals and polyvinyl chloride (PVC) were restricted in certain applications. At the time, Apple created a Regulated Substances Specification[1] that bound its suppliers to abide by its restrictions on hazardous substances. Restrictions were steadily increased, with its largest shift occurring in 2009 when nearly all uses of brominated flame retardants (BFR) and PVC were eliminated.

BFRs were commonly found in polymers, including printed circuit boards, cable jacketing, and other electrical components. BFRs were eliminated because some were found to be bioaccumulative or had endocrine disrupting properties. BFRs were replaced with safer, less hazardous phosphorous-based and metal hydroxide flame retardants, or eliminated altogether through the use of naturally flame retardant materials such as aluminum.

PVC was primarily used in cable jacketing in power cords and data cables. It was eliminated due to several lifecycle concerns, including that highly toxic chlorinated dioxins can be generated during end-of-life processing. PVC was replaced with non-halogenated thermoplastic elastomers.

Removal of BFRs and PVC were challenging since alternatives were not readily available at the time. The largest obstacle was identifying a replacement to PVC in AC power cords, where strict safety standards favored PVC and created barriers to its elimination. Apple worked with multiple material suppliers and tested dozens of different formulations until the right combination of performance and safety were achieved with lower toxicological and ecological risk than PVC. Apple then had to persuade dozens of safety agencies around the world to allow it to certify the alternative materials. Millions of PVC-free power cords are in use today with Apple products.

In addition to restrictions on PVC and BFRs, Apple also phased out its use of mercury in display backlighting, arsenic in glass, and beryllium from connectors and springs. Each of these substances had negative toxicological properties and was replaced with safer materials.

While Apple's efforts to eliminate targeted hazardous substances improved the safety of its products, eliminating substances of concern one-by-one has its limitations. The approach tends to be reactive to public or regulatory pressure, and can include only a small subset of chemical substances used in commerce. It equally restricts use of all materials containing the targeted element or compound regardless of the actual risk from its use. Finally, it can prompt a simplified and misguided view that any replacement free of the targeted substance is a safer material, which has the potential of leading to regrettable substitutions.

To overcome these limitations, Apple implemented a more comprehensive strategy that integrated evaluations of human and environmental health hazards of substances combined with toxicological risk assessments into material selection decisions during the product development process.

Integrating Full Material Disclosure and Toxicological Assessments

Apple's current strategy for safer materials is built upon the fundamental premise that comprehensive action cannot be taken without a full understanding of the toxicological hazards and risks of chemicals in products. A necessary prerequisite for hazard and risk assessment is to have full knowledge of the chemical composition of materials used in products and the lifecycle exposures associated with those chemicals.

However, this approach is not standard practice for the electronics industry. Most brands do not have an understanding of material composition and the associated toxicological risks of their products because no regulation directly requires an understanding of product composition. In addition, composition is generally claimed as confidential information or trade secrets of the supplier. Even if the data was readily available, most brands lack infrastructure to collect, process, and make decisions based on that information.

Full Material Disclosure (FMD)

To understand the material composition of products, Apple launched a Full Material Disclosure (FMD) program with the ambitious goal of documenting the chemical composition of every homogeneous material in every component of Apple products. While this is not a novel concept, especially for the cosmetics and other health-focused industries, it is in its nascent stages for the electronics industry. Success depends on overcoming significant technological, business process, and intellectual property concerns.

Apple made significant investments in custom software tools and new processes to enable suppliers to document the material identity and chemical composition for every homogeneous material in Apple purchased parts and components. This was a complex undertaking that required millions of dollars of investment and nearly three years to implement. In addition, Apple faced significant challenges collecting the full material disclosure data from suppliers. Accurate disclosures require suppliers to track the composition of materials through multiple tiers of their own supply chain, which does not occur consistently. Moreover, some suppliers claim material identity and composition information as their intellectual property and are unwilling to disclose. Obtaining accurate and complete disclosures is a multiyear effort involving business redesign, education, and trust-building through multiple tiers of the supply chain.

To date, Apple has collected well over 12,000 component compositions, or full material disclosures, for materials used in its products. Each disclosure goes through dozens of automated and manual checks for accuracy and completeness. Declarations that have known or suspected issues are rejected back to the supplier.

Toxicological Assessments

Following receipt of the full disclosure of ingredients on a material, Apple utilizes a comparative chemical hazard assessment framework, such as Clean Production Action's GreenScreen® for Safer Chemicals,[2] to assess the toxicological profile of each substance. This approach comprehensively evaluates each chemical across 18 different human health and environmental hazard endpoints, including carcinogenicity, reproductive toxicity, and skin sensitization potential. It enables Apple toxicologists to make material use decisions based on the toxicological properties of the material and its application in the product. While toxicological evaluations require significantly more effort to administer than past approaches that restricted individual or entire classes of substances, Apple has found that comprehensive hazard evaluations provide more meaningful data and context to product and material development decisions.

Evaluation of Process Chemicals

Apple's efforts have not been limited to materials that reside in the final product. For example, in 2014, Apple banned the use of benzene, n-hexane and chlorinated organic compounds in cleaners and degreasers from its final assembly processes. In 2016, Apple added toluene and N-methyl-2-pyrrolidone to its regulated substances specification and expanded the restrictions to all manufacturing cleaning, degreasing, and demolding processes.

Additionally, Apple has documented the chemical composition of key process chemicals, such as cleaners and degreasers, used at Apple's contract final assembly manufacturing sites. While these chemicals do not reside within the final manufactured product, an understanding of these substances was essential to ensure the safety of assembly workers. Apple toxicologists evaluated the constituents of each material according to the GreenScreen® framework and similar approaches. It was found that only a very small fraction of solvents used in cleaners and degreasers across all final assembly sites were classified as a chemical of high concern. Although proper exposure and safety controls were in place, Apple aggressively identified and implemented safer alternatives for each of these in order to mitigate potential future risk. Classification of solvents and degreasers according to hazard was an effective prioritization tool for finding safer materials.

Inclusion of a hazardous substance in a regulated substances specification is not sufficient to effectively restrict its use. Apple conducts extensive onsite assessments based on chemical uses, the manufacturing processes and the occupational exposure risks to ensure the highest standards of chemical management practices at its suppliers. These engagements are led by industrial hygienists and supported by toxicologists. During these engagements, Apple maps chemical usage, identifies potential health and safety risks, educates supplier staff on sound practices, and partners to evaluate safer alternatives to reduce and replace chemicals of concern. Hazard evaluations are conducted on all newly identified substances.

Apple Watch Case Study: Integrating Toxicology into Material Selection

Products in prolonged skin contact, such as Apple Watch, require more rigorous controls on material safety. With customers often wearing Apple Watch for more than 12 hours per day, every day, exposure is far greater than typical consumer electronic devices. Wearable technology potential brings higher risks to customers, increasing the importance of sound material selection decisions.

Recognizing the increased risk to its customers, Apple implemented stricter processes to control materials in potential skin contact by fully integrating toxicological assessments during the material selection process that occurs during the design of new products. Apple's process involved three steps:

1. Publication of a regulated substances specification specific to wearable devices
2. Material characterization testing to objectively evaluate conformity to the specification and characterize leachable substances for skin contact risks
3. Toxicological hazard and risk assessments based on full material disclosure to identify other risks

A detailed description of each step is provided in the following sections.

Publication of a regulated substances specification for wearables

Apple created a new specification restricting certain hazardous substances in wearable devices, as consumer exposure is greatest in this category of products, and regulatory limits are in general not available or may not be sufficiently protective for prolonged contact. The specification has the most restrictive limits on hazardous substances, with a key focus on dermal irritants and sensitizers in addition to regulatory restrictions. Irritants and sensitizers were in focus because customer skin reactions are the most commonly reported health issue for wearable products, such as jewelry.

Apple also modified its approach to limiting the concentration of hazardous substances. In some cases, restrictions for a given substance have two different thresholds: (i) maximum allowable limit (MAL), and (ii) threshold for toxicological review (TTR). If a sub-stance exceeds the MAL, the material is automatically rejected for use. If the material has a substance with a concentration lower than the MAL but higher than the TTR, an evaluation by Apple toxicologists is triggered. This review is necessary because the specification is application agnostic, and cannot reflect exposure. Therefore, a material's approval will depend on the expected exposure to the substance and the relevant toxicological endpoint of concern. This split threshold allows for more precision on evaluating safety of exposures to chemicals based on the relevant toxicological endpoint of concern under the use conditions of the material.

The regulated substances specification is distributed to material suppliers and contractual requirements obligate compliance. Nevertheless, compliance is not assumed. All materials undergo material characterization testing to validate compliance to the specification in the second step.

Materials characterization testing

Materials characterization testing is an essential process to ensure compliance to the regulated substances specification and to uncover any potentially hazardous substances that are present but not expressly listed in the specification. Materials characterization is broken down into the following sub-steps:

1. Measure the concentration of specific substances covered by Apple's regulated substance specification, and
2. Extraction testing in artificial sweat and other appropriate solvents to identify and quantify substances that leach out of the material. This process is modeled on extractable testing typically conducted by the cosmetics and medical device industries. In the case of metal components, the leach rate of metals that are potential skin sensitizers (e.g. nickel and cobalt) are measured in artificial sweat.

Materials characterization testing is specific to the material type, with some including tests for more than 180 regulated substances. Testing is conducted both in third party labs and Apple's internal lab. Since 2006, Apple's internal lab has grown to 20 times its original size, adding state of the art equipment to characterize materials, including inductively coupled plasma-mass spectrometry (ICP-MS), laser-induced breakdown spectroscopy (LIBS), ion chromatography (IC), high performance liquid chromatography (HPLC), and gas chromatography-mass spectrometry (GC-MS). While Apple continues to rely on third party laboratories to conduct verification testing, in-house test capability has increased the speed of evaluations and internal know-how while protecting product secrecy which are important to keep up with the rapid pace of new product development.

Toxicologists use the testing results to conduct risk assessments for material selection. Acceptable exposure levels are derived for the identified substances using data in the scientific literature and computational methods. Appropriate and conservative uncertainty (safety) factors are incorporated into the derivation of acceptable exposure levels to account for uncertainty inherent in the available toxicological data. The acceptable exposure level is then compared to an estimated consumer exposure level under conservative and appropriate use conditions of the material. If the consumer exposure level exceeds the acceptable exposure level, the material is not approved for use.

While this evaluation is cost and labor intensive and requires resources not usually found in the electronics industry, it is the most essential step to objectively and comprehensively evaluate safety. Characterizing materials without knowing the full composition requires a battery of testing for substances of concern combined with supplier statements. Higher quality assessments can be completed if the full chemical composition is known in advance.

Toxicological hazard and risk assessment based on Full Material Disclosure

In the third step, toxicological assessments are conducted based on material composition disclosure provided by the raw material supplier. This enables a theoretical evaluation of the hazards and risks associated with the material based on the declared ingredients and concentrations. In addition, it has the benefit of helping focus material characterization testing on potentially problematic areas and to rapidly determine if well-known hazardous substances are present in the formulation.

Apple has conducted hundreds of toxicological hazard and risk assessments with this approach for materials used in wearable devices. In cases where material suppliers were unwilling to provide Apple with a full material disclosure, an "escrow" model was used where the supplier disclosed the composition to a third party toxicology consultancy, which then completed a hazard evaluation for Apple. The hazard evaluation provided to Apple redacted the chemical composition, leaving only the hazard information. While this approach helps to overcome supplier concerns about the protection of trade secrets and confidential business information, direct access to the composition has significant benefits.

Material Safety Assessments

Material safety decisions are made by Apple toxicologists based on the aforementioned three steps. All materials intended for use in a prolonged skin contact application are required to follow this process before they are approved. The process is designed to be rapidly executed and with redundancy to ensure determinations can be made within the timelines associated with new product development. Lastly, it also avoids ethical concerns associated with in-vivo testing.

While the majority of testing is focused on individual materials or components in order to have the greatest specificity and isolate for variables, testing is also conducted on assembled units and products to account for material interactions and variability in assembly processes. Testing is also conducted on products that have undergone simulated life testing, in case expected use has an impact on safety.

Finally, Apple investigates any incident of reported skin irritation with board-certified dermatologists to identify the root cause and enable improvements in product design.

Conclusion

A great deal of care and research goes into selecting materials for all Apple products. Apple's process relies upon a combination of tools to assess and ensure exposure to hazardous chemicals is prevented or remains below conservative safety thresholds. The combination of substance restrictions, full material disclosure, comprehensive analytical testing, and use of toxicological risk assessments provides an effective means of ensuring manufacturing workers, customers, and recyclers can use and handle Apple products safely.

[1] "Apple Regulated Substances Specification, 069-0135,", Apple Inc., Cupertino, USA, Apple Inc., 2016 [Online]. Available: http://images.apple.com/environment/pdf/Apple_Regulated_Substances_Specification_March2016.pdf

[2] Clean Production Action, "GreenScreen® for Safer Chemicals Hazard Assessment Guidance, Version 1.3 (1e)", 2016.